From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

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NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	24.07.97
Applicant's or agent's file reference: RPI-035CPPC	IMPORTANT NOTIFICATION

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 96/06200	02/05/1996	04/05/1995

Applicant

UNITED STATES OF AMERICA AS REPRESENTED... et al

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

ENTERED

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LAHIVE & COCKFIELD
JUL 28 1997

Name and mailing address of the IPEA/	Authorized officer
European Patent Office D-80298 Munich Tel. (+49-89) 2399-0, Tx: 523656 epmu d Fax: (+49-89) 2399-4465	BY C. Vullo Telephone No. 8052

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
RPI-035CPPC		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 96/ 06200	02/05/1996	04/05/1995
International Patent Classification (IPC) or national classification and IPC		
C12N15/87		
Applicant		
UNITED STATES OF AMERICA AS REPRESENTED... et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consists of a total of _____ sheets.

3. This report contains indications and corresponding pages relating to the following items:

   I ☒ Basis of the report

   II ☐ Priority

   III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

   IV ☐ Lack of unity of invention

   V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

   VI ☐ Certain documents cited

   VII ☐ Certain defects in the international application

   VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
26/11/1996	24.07.97
Name and mailing address of the IPEA/	Authorized officer
European Patent Office D-80298 Munich Tel. (+49-89) 2399-0, Tx: 523656 epmu d Fax: (+49-89) 2399-4465	R. Großkopf
	Telephone No.

I. Basis of the report

1. This report has been drawn up on the basis of (Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.):

[x] the international application as originally filed.

[ ] the description, pages _____, as originally filed,
pages _____, filed with the demand,
pages _____, filed with the letter of _____,
pages _____, filed with the letter of _____,

[ ] the claims, Nos. _____, as originally filed,
Nos. _____, as amended under Article 19,
Nos. _____, filed with the demand,
Nos. _____, filed with the letter of _____,
Nos. _____, filed with the letter of _____,

[ ] the drawings, sheets/fig _____, as originally filed,
sheets/fig _____, filed with the demand,
sheets/fig _____, filed with the letter of _____,
sheets/fig _____, filed with the letter of _____.

. The amendments have resulted in the cancellation of:

[ ] the description, pages _____.
[ ] the claims, Nos. _____.
[ ] the drawings, sheets/fig _____.

[ ] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims _____	YES
	Claims 1,19 _____	NO
Inventive Step (IS)	Claims _____	YES
	Claims 2-18, 20-21 _____	NO
Industrial Applicability (IA)	Claims 1-19 _____	YES
	Claims _____	NO

2. CITATIONS AND EXPLANATIONS

1. A method for transfection of T cells with a nucleic acid molecule comprising a gene wherein the T-cells are contacted with a stimulatory agent prior to the transfection is already described in D1 (WO 94/29436; see e.g. page 21. section II).
Therefore, at least the general methods according to present Claims 1 and 19 are not novel (Article 33.2 PCT).
Moreover, and without going into detail, nearly all of the other embodiments of the dependent claims are also disclosed in D1 (i.e. especially the use of two different agents and several of the specific agents referred to in the dependent claims) and, consequently, said claims lack novelty.

2. A detailed examination of novelty and inventive activity of the dependent claims, however, at present has not taken place for the following reasons:

First, it appears as if an inventive concept of the present application which is based on the choice of the order of the stimulation and the transfection step, is no longer present. In view of this observation, also none of the features of the dependent claims (novelty provided) can re-establish an inventive activity.

Second, in view of the lack of novelty of the main claims, most of the dependent claims become "quasi-independent" and are, regardless the absence of any inventive activity, no longer connected between each other by a common inventive concept.
Thus, in absence of one independent main claim which is, at least, novel the remaining set of claims lacks unity. Consequently, a further examination can only take place either if a decision has been taken by the Applicant which of the features of the dependent claims should be examined (e.g. by integrating this feature into a new main claim), or if one or more examination fees have been paid for each of the features which is desired to be examined.

3. For the assessment of the present Claims 19 to 21 on the question whether they are industrially applicable, no unified criteria exist in the PCT. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but will allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.